

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO
ALL ACTIONS

Chief Mag. Judge Marianne B. Bowler

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION
TO COMPEL HHS ASP DOCUMENTS**

Plaintiffs' Motion to Compel the production of HHS ASP documents should be denied for the same reasons that the Track 1 Defendants' Motion for Protective Order precluding depositions on the ASP issue should be granted.¹ As explained more fully in Defendants' Motion for Protective Order filed on June 15, 2004, the discovery Plaintiffs seek is wholly irrelevant to this action and unnecessarily burdensome on Defendants. The documents Plaintiffs have requested relate to a new Medicare reimbursement system, based on a newly defined calculation known as "average sales price" or "ASP," that does not take effect until 2005 and for which the reporting obligations are still being developed by the relevant federal agency. Discovery into such prospective and unsettled regulatory requirements is unwarranted here,

¹ Plaintiffs' Motion to Compel should also be denied because their requests violate Local Rule 26.1(c), which prohibits Plaintiffs from serving more than "two (2) separate sets of requests for production" without a judicial order permitting them to do so. Plaintiffs previously served Defendants with document requests on December 3, 2003, December 19, 2003, and March 31, 2004. *See* Defs.' Mot. for Protective Order, at 5 n.3. Plaintiffs' request for HHS ASP and related documents is their *fourth* set of requests for production.

particularly given that the Track 1 Defendants have produced or are in the process of producing from the relevant time periods the “average manufacturer price” (“AMP”) data that Plaintiffs contend is a “close proxy” to ASP. In contrast to the uncertain and untested ASP data, Defendants have been generating AMP data for over a decade in connection with the Medicaid rebate program. In addition, the Track 1 Defendants have produced (or shortly will produce) underlying rebate, discount, chargeback and pricing data that should enable Plaintiffs to make any calculations they wish. Under all these circumstances, Defendants should not be put to the burden of producing ASP data, which will only confuse and expand the issues in this case.

ARGUMENT

While the Federal Rules generally allow for broad discovery, they do not permit discovery into matters outside the bounds and irrelevant to the allegations of the Complaint. *See, e.g., Public Serv. Co. of New Hampshire v. Hudson Light & Power Dep’t*, 938 F.2d 338, 346-47 (1st Cir. 1991) (district court properly refused to allow discovery into irrelevant matters); *Assoc. for Reduction of Violence v. Hall*, 734 F.2d 63, 67 (1st Cir. 1984) (district court has discretion under Rule 26(b)(1) to prevent discovery on grounds of irrelevance). Moreover, even where the information requested is relevant -- which it is not here -- this Court has the discretion to limit discovery where the burden of such discovery outweighs any likely benefit. *See Fed. R. Civ. P. 26(b)(2); Ameristar Jet Charter, Inc. v. Signal Composites*, 244 F.3d 189, 193 (1st Cir. 2001).

Plaintiffs argue (at 3) that ASPs are relevant to this action because they are “in effect a proxy for what the AWP would have been but for the scheme to report inflated AWPs” and as such are necessary for calculating and analyzing the purported “spread” between published AWPs and actual sales prices. But, as discussed in detail in Defendants’ Motion for Protective Order, at 5-7, ASP is not a “proxy” at all, but rather a new calculation -- never before

defined by statute or regulation or reported to any drug pricing publication -- that will not be used as a basis for any drug reimbursement until 2005. It is a work in progress about which there remains a tremendous amount of uncertainty, with numerous parties having submitted comments identifying significant defects in the proposed ASP calculation methodology. Such a new and untested measure of the future is irrelevant to any past misconduct alleged by Plaintiffs here, and the production of such data will only spawn unnecessary satellite litigation over its uncertain meaning.

While Defendants resist the production of ASP data, each Track 1 Defendant has produced or is in the process of producing “average manufacturer price” (“AMP”) data for each of the drugs at issue. AMP, unlike ASP, is defined by statute² and has been used by the government for many years and throughout the relevant time period identified in the Complaint to calculate rebates under the Medicaid program. *See* 42 U.S.C. § 1396r-8(c)(1). Plaintiffs contend that “AMPs are a close proxy to ASP.” Pls.’ Opp. to Mot. for Protective Order, at 11 n.7. Under these circumstances, Defendants’ production of AMP data, along with the rebate, discount, chargeback, and other pricing data that they have agreed to produce, should be more than sufficient to serve Plaintiffs’ professed purposes. These data should allow Plaintiffs to make the “spread” calculations that they claim they need without placing any additional burdens on Defendants, who are engaged in a massive discovery effort under exceedingly tight deadlines set by CMO 10. *See* Defs.’ Mot. for Protective Order, at 4-5.

In sum, given Defendants’ production of AMP and other pricing-related data from the relevant time period, Plaintiffs have no basis for also seeking Defendants’ ASP data. This

² AMP is defined as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.” 42 U.S.C. § 1396r-8(k)(1).

Court should reject Plaintiffs' attempt to further expand discovery into Defendants' ongoing efforts to comply with prospective regulatory requirements or the implementation of a reimbursement system that has yet to take effect.

CONCLUSION

For all of these reasons, and those stated in the Track 1 Defendants' Motion for Protective Order, Plaintiffs' Motion to Compel HHS ASP Documents should be denied.

REQUEST FOR ORAL ARGUMENT

Defendants request oral argument on Plaintiffs' Motion to Compel.

Respectfully submitted,

**ON BEHALF OF DEFENDANTS
IN THE ABOVE-CAPTIONED ACTION,**

BY: /s/ Seth B. Kosto _____

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DATE: July 16, 2004

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CERTIFICATE OF SERVICE

I hereby certify that on July 16, 2004, I caused a true and correct copy of Defendants' Opposition to Plaintiffs' Motion to Compel HHS ASP Documents to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2.

/s/
Ronald G. Dove, Jr.